

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/310,740	05/13/99	BROWN	S 37-49

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HM12/0313

EXAMINER

CHOI, F

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 03/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/310,740	BROWN ET AL.	
	Examiner	Art Unit	
	Frank I Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-186 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-186 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some * c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 12/19/00 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Objections

Claims 38-97, 99-119, 121-134, 136-145, 147, 149-153, 155, 157-161, 163-165, 167, 168, 170, 172-178, 180, 182, 183, 185, 186 are objected to because of the following informalities:

Dependent claims should begin with a "The" not an "A". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37-186 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims broadly claim a "substrate", however, it appears

that the Specification gives little direction as to what the substrate is. The only examples of a substrate which appear to be disclosed are a tablet core and the conveyor belt (Specification, Pg. 18. Pg. 19, lines 28-31). Further, the claims broadly claim a coating layer or cover, however, only two types appear to be disclosed, powdered and liquid, and only a few examples are disclosed as to the components of the coating layers or covers (Specification, Pgs. 20-28). As such, it appears that skilled artisan would not be able to immediately envision all the possible substrates and components and combinations thereof which could possibly fall within the scope of the broad limitations herein.

Claims 37-186 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specified examples in pgs. 20-28, does not reasonably provide enablement for the broad scope of the claims herein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. As indicated above, the claims broadly claim a substrate and coating layers or covers, however, it appears the limited direction is given as to the components of each. Further, one aspect of the invention is the electrostatic charge. However, the Specification gives little direction as to what substrates or compounds are susceptible to having an electrostatic charge so as to be suitable for the claimed

invention. Further, it is notoriously well known that different compounds have different requirements concerning solubility, compatibility, stability, etc. However, as indicated above, the Specification appears to give little direction as to active ingredients and excipients which would be suitable for the claimed invention. As such, in light of the above, a skilled artisan

would be required to do undue experimentation in order to make and/or use the invention commensurate in scope with the claims.

Claims 40-47, 59-66, 78-85, 94, 105-109, 110, 123-127, 1, 138, 146-161, 181-183 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims contain the term "such that" which renders the claims indefinite as it is uncertain whether the matter following is merely descriptive or a required limitation of the claims. Examiner suggests using "wherein".

Claim Rejections - 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 98, 113, 114, 115, 116, 166 are rejected under 35 U.S.C. 102(b) as anticipated by
or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schmidt (U.S. Pat. 4, 925,670).

Schmidt expressly discloses a method of preparing a dosage form on a removable substrate falling within the scope of applicant's claims (Column 5, lines 35068, Column 6, claims 1-9).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See also *In re May*, 197 USPQ 601, 607 (CCPA 1978).

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Claims 98, 100, 101, 103-109, 113-116, 146, 147, 154, 166, 181 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt (U.S. Pat. 4, 925,670).

Schmidt teaches methods of making solid dosage forms by coating an active agent or several layers onto a removable substrate (Column 2, lines 20-30, 50-55, Column 3, lines 33-44, Column 4, lines 18-28, Column 5, lines 20-27).

The difference between the cited reference and the claimed invention is that the cited reference does not expressly disclose a method of preparing a dosage form on a removable substrate having multiple layers. However, the cited reference amply suggest the same as dosage forms having multiple layers are well known in the art. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to use multiple layers to separate incompatible ingredients, provide a protective layer and/or have different release rates.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

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The following discussion applies as is relative to the above rejections. In the first instance, not every claim has a electrostatic or powder limitation. Second, the term "fused" does not appear to be defined, and as, such may include simple attachment of layer to substrate. The phrase "one dose of active material" does not distinguish the claims herein as it is well within the skill of one of ordinary skill in the art to prepare a single dosage form or multiple dosage forms depending on the number of dosage forms desired. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the elements of the apparatus) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further, the claims do not appear to clearly indicate that the substrate is the apparatus. The term "plurality of regions" does not appear to be defined and as such does not appear to exclude the composition or method in Schmidt. Finally, one of ordinary skill in the art would have been motivated to use several layers of the same active layer so as to obtain pulses of the active ingredient over time.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628.

FIC

March 12, 2001



JOHN PAK
PRIMARY EXAMINER
GROUP 1000

